



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

1773 '00 APR 14 A9:58

April 12, 2000

Gerie B. McDonald
President
Mikart, Incorporated
1750 Chattahoochee Ave., N.W.
Atlanta, GA 30318

Re: Docket No. 99P-4848/CP1

Dear Ms. McDonald:

This responds to your citizen petition, dated October 8, 1999, requesting that the Food and Drug Administration (FDA) determine whether carbinoxamine maleate 4 mg/5cc elixir was withdrawn from sale for reasons of safety or effectiveness and, if not, to include the drug in the "Discontinued Drug Product List" of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).

The FDA has reviewed its records and has determined that carbinoxamine maleate 4 mg/5cc elixir was not withdrawn from sale for reasons of safety or effectiveness. This determination allows the FDA to maintain carbinoxamine maleate 4 mg/5cc elixir in the "Discontinued Drug Product List" of the Orange Book.

Enclosed is a copy of the *Federal Register* notice announcing the FDA's determination. If you require any further information, please do not hesitate to call me at 301-594-2041.

Sincerely yours,

Mary Catchings
Regulatory Policy Staff (HFD-7)
Center for Drug Evaluation and Research

Enclosure

99P-4848

ANSI